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09/831,681	05/10/2001	Alexander James Wignore	2001-0878.ORI	7056

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

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Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/831,681
Filing Date: May 10, 2001
Appellant(s): WIGMORE, ALEXANDER JAMES

Mark J. Burns
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 02/28/05.

(1) *Real Party in Interest*

RD

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-5, 7-9, 16, 30 and 33-36 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

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(10) Grounds of Rejection

The 112, first paragraph rejection over claims 1-5, 7-9, 16, 30 and 33-36 has been withdrawn in view of applicant's argument.

The following ground of rejection is applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-9, 16, 30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watts et al. US 6,200,602.

Watts teaches a composition for enhanced uptake of polar drugs, including sodium cromoglycate, from the colon (see abstract, column 5, lines 33-35). The composition also comprise dispersing agent (surfactant) having HLB value between 1-20 (column 4, lines 20 through column 2, lines 1-4). The composition further comprises excipient, such as Avicel™ (microcrystalline cellulose), and can be formulated into capsule, tablet or pellets (column 6, lines 16-20). The dosage form can be coated to ensure that the tablet or pellet does not break-up and release the drug until it reaches the proximal colon (column 6, lines 21 through column 7, lines 1-27).

Watts does not teach the dissolve rates of the dosage form. However, Watts teaches the use of similar coating material (enteric coating), which only begin to dissolve when the dosage form entered the small intestine (column 6, lines 45-48). "When the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established". *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Therefore, it is the position of the examiner that the enteric coated tablet or pellet of Watts would have similar dissolve rates desired by the applicant. Accordingly, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable dissolve rate to obtain the claimed invention, because Watts teaches the advantageous results in the use of similar enteric-coated dosage form to ensure the release of drug in the small intestine.

It is noted that Watts does not teach the diameter size of the pellets. However, Watts teaches similar dosage form, e.g., enteric-coated pellets useful to deliver drug to the proximal colon (id). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus, it is the position of the examiner that the diameter size of the pellets would have been obvious to one of the skilled artisan.

Although Watts teaches the use of microcrystalline cellulose, Watts is silent as to the amounts being used. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is

evidence indicating such concentration is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Appellant's arguments filed 02/28/05 have been fully considered but they are not persuasive.

Appellant argues that Watts fails to teach a composition that rapidly disperse in the small intestine, possibly due to a gel that forms about the drug when exposed to intestinal fluid. In response to appellant's argument that the reference fails to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., a composition that *rapidly disperse in the small intestine*) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Appellant argues that nowhere does Watts teach or suggest the claimed ratios of disintegrant material to chromone. Such ratio criticality of the disintegrant to chromone ratios is described at page 17, lines 10-23 of the specification, as well as the Wigmore Declaration dated 05/29/03. In response to applicant's argument, the Declaration filed 05/29/03 has been carefully reviewed, however, it is noted that the Declaration does not show a side-by-side comparison between the claimed invention and those of Watts.

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The Declaration has not shown the dosage form taught by Watts does not have the same bioavailability as the claimed invention. Applicant's attention is called to column 8, lines 1-67, where Watts also teaches the desirability to increase drug absorption in the GI tract. Accordingly, it would have been obvious for one of ordinary skill in the art to modify the dosage form of Watts with the expectation of at least similar result.

Appellant argues that Watts does not teach or suggest the chromone dissolution rates recited in claim Groups I, III, and IV. In response to appellant's argument, the dissolution rates for a well known disintegrant (microcrystalline cellulose as taught by Watts and claimed by applicant) would be routinely determined by one of ordinary skill in the art. Furthermore, independent claims of Groups I, III, and IV are not drawn to tablets. Therefore, the Declaration was not found to be persuasive.

For the above reasons, it is believed that the rejections should be sustained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

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Respectfully submitted,

ST
Susan T. Tran
Examiner
Art Unit 1615

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May 12, 2005

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